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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,894	04/27/2001	Lu-Kwang Ju	5277	5277
39905	7590	08/30/2005	EXAMINER	
ROETZEL AND ANDRESS 222 SOUTH MAIN STREET AKRON, OH 44308			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 08/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/830,894	Applicant(s) JU, LU-KWANG	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2005.
- 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-34, 70 and 105-112 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-34, 70 and 105-112 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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***DETAILED ACTION***

The application should be reviewed for errors and conformity with domestic practice.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

The amendment filed 7/7/05 is acknowledged. Claims 1-4, 6-34, 70 and 105-112 are being considered on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 107 and 110-112 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 107 and 111 are vague, indefinite and confusing in the list of biosurfactants recited. For example, the use of terms such as "gramicidins", "lipopolysaccharides", "subtilisin", "cerlipin", "poly-saccharide-proteins" and "fimbriae", etc. is improper in this context. For example, "fimbriae" are structures on cells, and "lipopolysaccharide" is not an art recognized term. The characterization of "gramicidin" or "subtilisin" as a biosurfactant is not proper. These antibiotics do not appear to be biosurfactants. The nature of "cerlipin" could not be determined. The intended meaning of "poly-saccharide-proteins" is unclear. Is "glycoprotein" intended? It is unclear that all glycoproteins are properly biosurfactants.

Correction and clarification is required.

Claim 110 is confusing in the recitation "at least one at least one".

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 10, 16-19, 21, 28, 31-34, 70, 109-111 are rejected under 35 U.S.C. 102(b) as being anticipated by Robertson *et al.* (Appl. Environ. Microbiol., 1988. Vol. 54, pages 2812-2818) for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a process of making a biological product with a microorganism including bacteria, yeasts, molds and archaea in a medium containing an alternative oxidant source and under anaerobic conditions such that at least a portion of the population consumes said alternative oxidant at least a portion of the production process.

Robertson *et al.* disclose a process of making a biological product with *T. pantotropha* wherein if the oxygen within the culture medium is less than the maximum rate of oxygen replenishment to the culture medium, the microorganisms will substantially utilize oxygen for cellular respiration, and when the oxygen requirements for cellular respiration of the strain within the culture medium is greater than the maximum rate of oxygen supply to the culture medium, then at least a portion of the microorganism concentration within the culture medium will utilize the alternative oxidant source for cellular respiration during at least a part of the production process. See, e.g., page 2814. The electron acceptors are oxygen, nitrate and/or nitrite. See, e.g., Table 3. The strain has the ability to produce biopolymers such as proteins, enzymes and fatty acids.

***Response to Arguments***

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Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants argue that the invention is not anticipated because Robertson *et al.* is not concerned with the production and recovery of a biological product, but rather with certain determinations. However, this is not persuasive of error in the rejection, because at least biomass, a biological product, is produced and recovered to obtain the results of Table 2, page 2814.

Claims 1-4, 6-34, 70 and 105-112 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robertson *et al.* taken with Wendt *et al.*, Brock and Wagner *et al.* for the reasons as stated in the last Office action and the further reasons below.

The claims are directed to a process of making a biological product with a microorganism including bacteria, yeasts, molds and archaea in a medium containing an alternative oxidant and under anaerobic conditions at least a portion of the population consumes said alternative oxidant at least a part of the production process.

Robertson is discussed *supra*.

The reference differs from the claimed invention in the use of *Pseudomonas* strains.

However, Wendt *et al.* disclose a process for the production of a biological product with cells of a microorganism including *Pseudomonas* (col. 4, lines 58-64) under aerobic and anaerobic conditions in the presence of alternative oxidant sources such as nitrates such that the strain uses the alternative oxidant source when the demand of oxygen exceeds the supply. See, e.g., col. 6, lines 27-60.

The reference differs from the claimed invention in that nitrate is the only oxidant or electron acceptor disclosed for anaerobic respiration. However, Brock discloses a variety of such oxidants, including fumarate, sulfate, sulfur, ferric ion and nitrite (See, e.g., pages 113-114).

The substitution of nitrate or another ion with of salts or acids as the source of the respective ion is deemed to be well within the ordinary skill in the art, particularly since the respective ions are generally provided as a salt in an aqueous nutrient medium environment.

The references further differ from the invention as claimed in the use of small acids or fatty acids in the medium. However, Wagner *et al.* adequately demonstrate that it is routine in

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the art to provide nutrient media containing small acids, such as malonate, succinate, pyruvate or malate, or fatty acids such as stearic acid for microorganisms, including *Pseudomonas*. (See, e.g., col. 3). The Wagner *et al.* reference also addresses the use of nutrient limitation in the cultivation of bacteria, specifically by limiting magnesium or nitrogen for the production of rhamnolipids with *Pseudomonas* (See, e.g., Examples 2-3).

One of ordinary skill in the art would have had a reasonable expectation of success in obtaining a biological product by cultivation of a microorganism in the presence of an alternative oxidant source under aerobic conditions followed by anaerobic conditions using a variety of carbon sources and the limitation of a variety of nutrients to boost yields of a desired product depending on the specific microorganism to be cultured and/or the product to be produced.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of cultivation of Robertson *et al.* by using *Pseudomonas* strains as taught by Wendt *et al.* and further by the substitution of nitrate by other oxidants, as suggested by Brock, when the oxygen demand exceeds the oxygen supply, as well as the use of nutrient limitation and various carbon substrates, as suggested by the teachings of Wagner *et al.* for the expected benefit of maximizing the production of useful biological products produced by a microorganism suitable for use in the pharmaceutical industries and for foods or feed, for example.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention.

Applicant argues that neither Wendt nor Brock relied upon by the Examiner teach or suggest the production and recovery of a biological production from a microorganism, and that

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Wagner does not relate to aerobic/anaerobic processes. This argument is erroneous in that at least Wendt is concerned with the production of the biological product of clean water, which is substantially nitrate-free and which has an ecologically acceptable BOD level. Thus the biological product is clearly recovered.

In addition, it must be noted that "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." *In re Merck & Co. Inc.*, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." *In re Gorman*, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

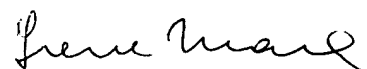
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in cursive script, appearing to read "Irene Marx".

Irene Marx  
Primary Examiner  
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